DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

SEP 30 2002

NADA 139-236

W.E. Lloyd, DVM, Ph.D., CEO
Lloyd, Inc
604 West Thomas Ave.
P.O. Box 130
Shenandoah, IA 51601-0130

Dear Dr. Lloyd:

This is in reference to your Annual Report submission dated July 31, 2001, including your distributor's labeling produced by [redacted] for Cervizine (xylazine) Injectable Sedative and Analgesic for Use in Horses and *Cervidae* (Fallow Deer, Mule Deer, Sika Deer, White-Tailed Deer and Elk), NADA 139-236.

In review of the package labeling, we have found the following statement, required by the currently approved label, to be omitted from the CAUTION section: "Do not use in *Cervidae* less than 15 days before or during the hunting season." The statement has been omitted from the bottle label, package insert, and box container labels. This omission causes your product to be unsafe within the meaning of section 512 (a)(1)(B) of the Federal Food, Drug, and Cosmetic Act and adulterated under section 501 (a)(5).

We request that you notify your distributor of this discrepancy and revise all associated labeling and promotional materials according to the currently approved label. Additionally, please submit the revised labeling pursuant to Title 21 Code of Federal Regulations section 510.300(b)(3) as soon as possible, or in any event within 30 days of the receipt of this letter. If you have any questions, you may contact us at (301) 827-6642.

Sincerely yours,

[redacted]

Mohammad I. Sharar, DVM, M.Sc.
Team Leader, Marketed Product Scientific
and Regulatory Review Team II, HFV-216
Division of Surveillance
Center for Veterinary Medicine